

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the following remarks.

**I.      Status of the Claims**

Claims 1-22, 24-30, 32-34, 36, 38-41, 43 and 46-56 are currently pending in the application, with claims 1, 24-25, 32-33, 36 and 54-56 being the independent claims. Claims 23, 31, 35, 37, 42 and 44-45 are canceled. Claims 1-22, 24-30, 32-34, 38 and 46-56 are withdrawn from consideration pursuant to a Restriction/Election requirement. Thus, claims 36, 39-41 and 43 are currently under consideration.

**II.     The Rejection Under 35 U.S.C. § 102**

The Office Action, at page 3, rejects claims 36, 38-41 and 43 as allegedly being anticipated by U.S. Patent Application Publication No. US 2005/0037983 A1 to Dinan *et al.* (“Dinan”). Applicants respectfully traverse this ground of rejection.

**A.      Summary of the Claimed Invention**

The presently claimed invention is directed to a method of treating major depression comprising administering a therapeutically effective amount of a pharmaceutical composition comprising an agonist of ATP-gated ion channel purinergic receptor P2X7 (P2X7R) activity to a subject suffering from major depression. The present application claims the priority benefit of US Provisional Application No. 60/474,232, filed on May 30, 2003, and US Provisional Application No. 60/501,011, filed on September 9, 2003, which disclose a method of treating an affective disorder, including depression, by administering an agonist of the P2X7R.

**B.      Dinan Priority Documents Fail to Teach Each and Every Element of the Claimed Invention**

The ‘983 application to Dinan was filed on March 11, 2004, after the priority date of the present application, and claims the priority benefit of US Provisional Application No.

60/453,786, filed on March 11, 2003, and US Provisional Application No. 60/459,073, filed on March 31, 2003.

The ‘983 application to Dinan does not constitute prior art, as the provisional patent applications whose benefit Dinan claims fail to disclose or suggest methods for the treatment of major depression comprising the use of agonists of ATP-gated ion channel purinergic receptor P2X7.

In fact, Dinan ‘786 provisional application discloses a method for treating depression by combining an antidepressant drug chosen from tricyclic and quadraacyclic antidepressants, monoamine oxidase inhibitors (MOAIs), selective serotonin reuptake inhibitors (SSRIs) and serotonin/nonadrenaline reuptake inhibitors (SNRIs) with an anti-inflammatory drug chosen from salicylates, such as aspirin, arylalkanoic acids, such as ibuprofen, anthranilic acids, such as mefenamic acid, pyrazoles, such as phenylbutazone, cyclic acetic acids, such as indomethacin, and oxicams, such as piroxicam. The specification of the present application clearly teaches that these antidepressant drugs possess shortcomings, including long latency until response, high degree of non-responders and undesirable side effects (*see paragraph [0005]* at page 1 of the published patent application US 2005/0147604). Nowhere does the ‘786 provisional application disclose a method for treating depression comprising the use of agonists of ATP-gated ion channel purinergic receptor P2X7.

Similarly, Dinan ‘073 provisional application discloses a method of treating IFN- $\alpha$ -induced depression in patients suffering from hepatitis C by using a combination of a non-steroidal anti-inflammatory drug chosen from salicylates, such as aspirin, arylalkanoic acids, such as ibuprofen, anthranilic acids, such as mefenamic acid, pyrazoles, such as phenylbutazone, cyclic acetic acids, such as indomethacin, and oxicams, such as piroxicam, with a standard antidepressant, such as SSRI, MOAI or an tricyclic antidepressant. Thus, the ‘073 provisional application fails to disclose a method of treating major depression comprising the use of agonists of ATP-gated ion channel purinergic receptor P2X7.

Accordingly, at least for the reasons stated above, Dinan fails to anticipate the claimed invention and the rejection is improper. Reconsideration and withdrawal of this ground of rejection are therefore respectfully requested.

## CONCLUSION

All of the stated grounds of rejection have been properly traversed or rendered moot. Thus, the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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